

ALLEGED SHIPMENT: On or about January 2, February 2, and March 9, 1951, by the Pitman-Moore Co., from Indianapolis, Ind.

PRODUCT: 40 bottles of *Estrotron* at Seattle, Wash. Examination showed that the product contained not more than 1.18 milligrams of estrogenic ketosteroids per cubic centimeter.

LABEL, IN PART: (Bottle and carton) "10 cc. Size * * * *Estrotron*, 2 mg. (20,000 I. U.) per cc. in Peanut Oil. A highly purified estrus producing extract from the urine of pregnant mares, consisting primarily of estrone with smaller quantities of naturally occurring estrogens, dissolved in Peanut Oil and standardized to 20,000 I. U. of activity per cc."

NATURE OF CHARGE: Adulteration, Section 501 (c), the strength of the article differed from that which it was represented to possess, namely, 2 milligrams of estrogenic ketosteroids per cubic centimeter.

Misbranding, Section 502 (a), the following statements in the labeling of the article were false and misleading as applied to an article which contained less than the declared amount of estrogenic ketosteroids per cubic centimeter: (Bottle and carton label) "* * * *Estrotron*, 2 mg. (20,000 I. U.) per cc. * * * consisting primarily of estrone with smaller quantities of naturally occurring estrogens * * * standardized to 20,000 I. U. of activity per cc. * * *" and (accompanying leaflet entitled "*Estrotron*") "* * * containing 2 mg. of estrogenic substance per cc. equal in estrogenic activity to 20,000 I. U. per cc."

DISPOSITION: June 18, 1951. Default decree of condemnation and destruction.

3514. Adulteration and misbranding of Premestrone (conjugated estrogens).

U. S. v. 197 Bottles * * *. (F. D. C. No. 30734. Sample No. 10119-L.)

LIBEL FILED: April 9, 1951, Eastern District of Michigan.

ALLEGED SHIPMENT: On or about January 9, 1951, by the Doctors' Mutual Service Co., from Glendale, Calif.

PRODUCT: 197 bottles of *Premestrone* (conjugated estrogens) at Detroit, Mich. Examination showed that the total amount of estrogens actually present in the article was equivalent to 0.22 mg. of sodium estrone sulfate per tablet.

LABEL, IN PART: "*Premestrone* 0.4 mg. 90 Tablets Estrogenic Substances (Water Soluble). Also Known As Conjugated Estrogens (Equine). * * * Formulated And Distributed By Specific Bio-Chemicals Glendale, California."

NATURE OF CHARGE: Adulteration, Section 501 (c), the strength of the article differed from that which it was represented to possess, namely, 0.4 mg. of estrogens in their water-soluble form expressed as sodium estrone sulfate.

Misbranding, Section 502 (a), the label statement "Each tablet contains 0.4 mg. of estrogens in their water soluble form expressed as sodium estrone sulfate" was false and misleading as applied to an article which contained 0.22 milligram of sodium estrone sulfate per tablet.

DISPOSITION: June 12, 1951. Default decree of condemnation and destruction.

3515. Adulteration and misbranding of Hemotene tablets. U. S. v. 148 Bottles, etc. (F. D. C. No. 31181. Sample No. 16763-L.)

LIBEL FILED: June 7, 1951, Southern District of California; amended libel filed June 28, 1951.

ALLEGED SHIPMENT: On or about December 30, 1950, and March 2, 1951, by the Midwest Chemical Development Corp., from Cleveland, Ohio.

PRODUCT: *Hemotene tablets*. 148 bottles, each containing 270 tablets, and 443 bottles, each containing 90 tablets, at Los Angeles, Calif. Analysis showed that the article contained substantially less than the stated amount of vitamins C and D.

LABEL, IN PART: (Bottle) "Hemotene With Organic Iron and B-12."

NATURE OF CHARGE: Adulteration, Section 501 (c), the strength of the article differed from that which it purported and was represented to possess, namely, 120 milligrams of vitamin C and 2,000 U. S. P. units of vitamin D.

Misbranding, Section 502 (a), the label statements "Six Hemotene Tablets provide: * * * Vitamin C 120 milligrams Vitamin D 2000 U. S. P. Units * * * Six tablets supply * * * M. D. R. * * * 4 times that of Vitamin C and 5 times that of Vitamin D" were false and misleading as applied to an article containing less than the stated amounts of vitamins C and D. Further misbranding, Section 502 (a), the label designation "Hemotene With Organic Iron and B-12" was false and misleading. The label designation represented and suggested that the article, because of its vitamin B₁₂ content, was effective in the treatment of nutritional anemia due to iron deficiency, whereas the article, because of its vitamin B₁₂ content, was not effective in the treatment of such condition.

DISPOSITION: July 27, 1951. Default decree of condemnation and destruction.

3516. Adulteration of grindelia. U. S. v. 6,666 Pounds * * *. (F. D. C. No. 30944. Sample No. 24012-L.)

LABEL FILED: May 8, 1951, Southern District of New York.

ALLEGED SHIPMENT: On or about January 2, 1951, by J. G. Olvey & Associates, from Colusa, Calif.

PRODUCT: 6,666 pounds of *grindelia* in 31 unlabeled bales at New York, N. Y. Examination of 6 samples showed that the article contained 25%, 25%, 50%, 12.5%, 12.5%, and 33.3% of stems over 2 mm. in diameter, respectively, in the 6 samples.

NATURE OF CHARGE: Adulteration, Section 501 (b), the article purported to be and was represented as "Grindelia," a drug the name of which is recognized in the National Formulary, an official compendium, and its quality fell below the official standard since the article contained more than 10 percent of its stems over 2 mm. in diameter, the maximum permitted by the standard.

DISPOSITION: June 21, 1951. The Meer Corp., New York, N. Y., claimant, having consented to the entry of a decree, judgment of condemnation was entered and the court ordered that the product be released under bond for relabeling, under the supervision of the Federal Security Agency, so that each bale would show its respective stem content, together with the stem content permitted by the National Formulary.

3517. Adulteration and misbranding of prophylactics. U. S. v. 21 Gross * * *. (F. D. C. No. 31419. Sample Nos. 16956-L, 16962-L.)

LABEL FILED: July 2, 1951, Southern District of California.

ALLEGED SHIPMENT: On or about February 7, April 21, and May 12, 1951, by the Ivers Lee Co., from Newark, N. J.